



11-10-04

Attorney's Docket No.: 17737-003US1/3703US

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PCT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Borody, Thomas J., *et al.*  
Intl. Appl. No.: PCT/AU03/00257  
Serial No. : 10/506,728  
Filed : September 3, 2004  
Cust. No. : 20985  
Title : ELECTROLYTE PURGATIVE

Art Unit : Unknown  
Examiner : Unknown  
Conf. No. : Unassigned

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Dear Sir:

Transmitted herewith are an Information Disclosure Statement and Forms PTO-1449 (3 pages) and cited references for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a first Office Action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:



The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie L. Seidman  
Reg. No. 33,779

Attorney Docket No. 17737-003US1/3703US

**Address all correspondence to:**

Stephanie L. Seidman  
Fish & Richardson P.C.  
12390 El Camino Real  
San Diego, California 92130  
Telephone: (858) 678-5070  
Facsimile: (202) 626-7796  
email: seidman@fr.com

**CERTIFICATE OF MAILING BY "EXPRESS MAIL"**  
"Express Mail" Mailing Label Number EV 399295451

Date of Deposit November 8, 2004

I hereby certify that this paper is being/deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie L. Seidman

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**INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§1.97-1.98**

Dear Sir:

Because this Information Disclosure Statement is filed before the receipt of a First Office Action on the Merits for the above-captioned application a fee is not required. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1050.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (2 pages) and copies of the cited references (excluding U.S. patents) are provided herewith in connection with the above-captioned application.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"  
"Express Mail" Mailing Label Number EV 399295451  
Date of Deposit November 8, 2004  
I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and is addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA, 22313-1450.

Stephanie L. Seidman

Applicant : Thomas Julius **[REDACTED]** Cody, et al.  
Intl. Appl. No.: PCT/AU03/0057  
Serial No. : 10/506,728  
Filed : September 3, 2004  
Information Disclosure Statement

Attorney Docket No.: 17737-003US1/3703

The documents cited on the Form PTO-1449 are in the English language, with the exception of items noted below. Items, AV and AW (patent serial numbers RU 2098100 and JP 05306221, respectively) are in the Russian and Japanese language, and are supplied with English language Derwent abstracts (items BA and BB, respectively). Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references is effective as prior art against the subject application. In accordance with 37 C.F.R. 1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. 1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and make them of record in the file history of the above-captioned application.

Respectfully submitted,

  
Stephanie L. Seidman  
Reg. No. 33,779

Attorney Docket No. 17737-003US1/3703US

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Stephanie L. Seidman  
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Facsimile: (202) 626-7796  
email: seidman@fr.com

Substitute Form PTO-1449 (Modified)		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17737-003US1/3703US	Application No. 10/506,728
<b>List of Patents and Publications for Applicant's Information Disclosure Statement</b>  (37 CFR §1.98(b))		Applicant Thomas Julius Borody, <i>et al.</i>		
		Filing Date September 3, 2004	Group Art Unit Unknown	

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
/A.H./	AA	20030180260	9/25/2003	Clancy <i>et al.</i>	424	934	5/9/2003
	AB	20040009961	1/15/2004	Borody	514	171	6/13/2003
	AC	20040028689	2/12/2004	Borody	424	184.1	8/4/2003
	AD	20020035075	3/21/2002	Borody	514	28	7/6/2001
	AE	20040038329	2/26/2004	Clancy <i>et al.</i>	435	30	7/31/2003
	AF	5196205	3/23/1993	Borody	424	653	7/12/1990
	AG	5274001	12/28/1993	Borody	514	474	7/17/1990
	AH	5443826	8/22/1995	Borody	424	93.3	8/6/1993
	AI	5476669	12/19/1995	Borody	424	653	8/31/1992
	AJ	5519014	5/21/1996	Borody	514	159	7/17/1994
	AK	5858403	1/12/1999	Borody <i>et al.</i>	424	456	10/31/1996
	AL	6103268	8/15/2000	Borody <i>et al.</i>	424	489	8/15/2000
	AM	6121250	9/19/2000	Nishiyama <i>et al.</i>	514	57	9/4/1998
	AN	6132767	10/17/2000	Borody <i>et al.</i>	424	456	10/17/2000
	AO	6277836	8/21/2001	Borody	514	159	11/17/1999
	AP	6426338	7/30/2002	Borody	514	159	12/17/1999
	AQ	6475518	11/5/2002	Baumgart	424	451	2/1/2002
↓	AR	6489317	12/3/2002	Borody	514	197	11/20/2000
	AS	6551632	4/22/2003	Borody	424	780	7/6/2001
/A.H./	AT	6645530	11/11/2003	Borody	424	543	6/7/1995

**Foreign Patent Documents or Published Foreign Patent Applications**

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation
							Yes No
/A.H./	AU	EP0397689	11/22/1990	EP	A61K	04700	
↓	AV	EP0433299	6/26/1991	EP	A61K	03902	
/A.H./	AW	EP0439453	8/7/1991	EP	A61K	03324	

Examiner Signature /Andriae Holt/	Date Considered 06/20/2008
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		Filing Date September 3, 2004	Group Art Unit Unknown	

### Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation Yes	Translation No
/A.H./	AX	EP0554291	8/11/1993	EP	A61K	03160		
	AY	EP0771562	5/7/1997	EP	A61K	031185		
	AZ	JP 05306221	11/19/1993	Japan	A61K	31/19	X*	
	BI	RU 2098100	12/10/1997	Russia	A61K	33/14	X*	
	BB	WO0001378	1/13/2000	PCT	A61K	031015		
	BC	WO0180852	11/1/2001	PCT	A61K	031192		
	BD	WO0197821	12/27/2001	PCT	A61K	03574		
	BE	WO0203065	1/10/2002	PCT	G01N	03353		
	BF	WO0207741	1/31/2002	PCT	A61K	03574		
	BG	WO2003061767	7/31/2003	PCT	A61P	03104		
	BH	WO2004070043	8/19/2004	PCT	C12N	0110		
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	BJ	WO8605981	10/23/1986	PCT	A61K	03129		
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	BL	WO8905659	6/29/1989	PCT	A61K	04700		
	BM	WO9001335	2/22/1990	PCT	A61K	03902		
	BN	WO9206690	4/30/1992	PCT	A61K	03160		
	BO	WO9602236	2/1/1996	PCT	A61K	00920		
	BP	WO9611014	4/18/1996	PCT	A61K	03574		
	BQ	WO9843667	10/8/1998	PCT	A61K	03904		
	BR	WO9850043	11/12/1998	PCT	A61K	03160		
/A.H./	BS	WO9956749	11/11/1999	PCT	A61K	031445		

X\*= An English Language Derwent Abstract is Provided

### Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
/A.H./	BT	Altomare DF, Memeo V, "Colonic explosion during diathermy colotomy. Report of a case", <i>Diseases Colon Rectum Mar</i> ; 36(3):291-2 (1993)
/A.H./	BU	Andrews PJ, Borody TJ, "Putting back the bugs': bacterial treatment relieves chronic constipation and symptoms of irritable bowel syndrome", <i>Med J Aust. Nov 1;159(9):633-4</i> (1993)

Examiner Signature /Andriae Holt/	Date Considered 06/20/2008
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		Filing Date September 3, 2004	Group Art Unit Unknown	

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Design. ID	Document		
/A.H./	BV	Arieff AI, Llach F, Massry SG, "Neurological manifestations and morbidity of hyponatremia: correlation with brain water and electrolytes", <i>Medicine (Baltimore) Mar;55(2):121-9</i> (1976)		
	BW	Borody TJ, "Flora Power-- fecal bacteria cure chronic C. difficile diarrhea", <i>Am J Gastroenterol. Nov;95(11):3028-9</i> (2000)		
	BX	Borody TJ, "Helicobacter pylori eradication failure--'salvage' therapies needed", <i>Ital J Gastroenterol Hepatol. Aug;30(4):375-7</i> (1998)		
	BY	Borody TJ, Andrews P, Jankiewicz E, Ferch N, Carroll M, "Apparent reversal of early gastric mucosal atrophy after triple therapy for Helicobacter pylori", <i>Am J Gastroenterol. Aug;88(8):1266-68</i> (1993)		
	BZ	Borody TJ, Ashman O., "Lactoferrin: milking ulcers?", <i>Dig Liver Dis. Oct;35(10):691-3.</i> (2003)		
	CA	Borody TJ, Brandl S, Andrews P, Ferch N, Jankiewicz E, Hyland L, "Use of high efficacy, lower dose triple therapy to reduce side effects of eradicating Helicobacter pylori", <i>Am J Gastroenterol. Jan;89(1):33-8</i> (1994)		
	CB	Borody TJ, George L, Andrews P, Brandl S, Noonan S, Cole P, Hyland L, Morgan A, Maysey J, Moore-Jones D, "Bowel-flora alteration: a potential cure for inflammatory bowel disease and irritable bowel syndrome?", <i>Med J Aust. May 15;150(10):604</i> (1989)		
	CC	Borody TJ, George LL, Brandl S, Andrews P, Lenne J, Moore-Jones D, Devine M, Walton M, "Helicobacter pylori eradication with doxycycline-metronidazole-bismuth subcitrate triple therapy", <i>Scand J Gastroenterol. Apr;27(4):281-4</i> (1992)		
	CD	Borody TJ, Shortis NP, Reyes E, "Eradication therapies for Helicobacter pylori", <i>J Gastroenterol. 33 Suppl 10:53-6</i> (1998)		
	CE	Borody TJ, Warren EF, Leis S, Surace R, Ashman O, "Treatment of ulcerative colitis using fecal bacteriotherapy", <i>J Clin Gastroenterol. Jul;37(1):42-7</i> (2003)		
	CF	Borody TJ, Warren EF, Leis SM, Surace R, Ashman O, Siarakas S., "Bacteriotherapy using fecal flora: toying with human motions", <i>J Clin Gastroenterol Jul;38(6):475-83</i> (2004)		
	CG	Cohen CD, Keuneke C, Schiemann U, Schroppel B, Siegert S, Rascher W, Gross M, Schlendorff D, "Hyponatraemia as a complication of colonoscopy", <i>Lancet Jan 27;357(9252):282-3</i> (2001)		
	CH	de Boer WA, Borody TJ, "Treatment failures and secondary resistance to antibiotics. A growing concern in Helicobacter pylori therapy", <i>Dig Liver Dis. Nov;32(8):673-5</i> (2000)		
	CI	Derwent Abstract Accession No. 93-408836, Class B05, JP 05306221 A (Horii Yakunhin Kogyo KK) 11/19/93 Abstract Only"		
	CJ	Derwent Abstract Accession No. 98-375395, Class B05, RU 2098100 C1 (Maksimova <i>et al.</i> ) 12/10/97 Abstract Only"		
	CK	Fincher RK, Osgard EM, Jackson JL, Strong JS, Wong RK, "A comparison of bowel preparations for flexible sigmoidoscopy: oral magnesium citrate combined with oral bisacodyl, one hypertonic phosphate enema, or two hypertonic phosphate enemas", <i>Am J Gastroenterol Aug;94(8):2122-7</i> (1999)		
↓	CL	Fraser CL, Kucharczyk J, Arieff AI, Rollin C, Sarnacki P, Norman D, "Sex differences result in increased morbidity from hyponatremia in female rats", <i>Am J Physiol. Apr;256(4 Pt 2):R880-5</i> (1989)		
/A.H./	CM	Melton JE, Patlak CS, Pettigrew KD, Cserr HF "Volume regulatory loss of Na, Cl, and K from rat brain during acute hyponatremia", <i>Am J Physiol. Apr;252(4 Pt 2):F661-9</i> (1987)		

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